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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,172	12/21/2001	Yoichi Takahama	322732000401	2837

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,172	TAKAHAMA ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *31-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

DETAILED ACTION

Claims 31-43 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 32-35, drawn to a diagnostic agent for HCV infection comprising a solid sensitized with a mixture of a genetic recombinant HCV antigens comprising a nonstructural region and synthesized HCV antigens comprising structural and nonstructural HCV peptide proteins of core, NS4 and NS5, wherein the recombinant HCV antigen is directly sensitized onto the solid phase, classified in class 424, subclass 228.1.

II. Claims 37-38 (i), drawn to a diagnostic agent for HCV infection comprising a solid sensitized with a mixture of a genetic recombinant HCV antigens comprising a nonstructural region and one synthesized HCV peptide antigen of HCV core that is conjugated with a carrier protein, classified in class 424, subclass 193.1.

III. Claims 37-38 (ii), drawn to diagnostic agent for HCV infection comprising a solid sensitized with a mixture of a genetic recombinant HCV antigens comprising a nonstructural region and one synthesized HCV antigen peptide of HCV NS4 peptide that is conjugated with a carrier protein, classified in class 424, subclass 192.1.

IV. Claims 37-38 (iii), drawn to a diagnostic agent for HCV infection comprising a solid sensitized with a mixture of a genetic recombinant HCV antigens comprising a nonstructural region and one synthesized HCV antigen comprising NS5 non-structural peptide that is conjugated with a carrier protein, classified in class 432, subclass 192.1.

V. Claim 39, drawn to a diagnostic agent for HCV infection comprising a solid sensitized with a mixture of a genetic recombinant HCV antigens comprising a nonstructural region and synthesized HCV peptide antigens of core, NS4 and NS5 non-structural peptides that are conjugated with carrier proteins, classified in class 432, subclass 192.1.

2. Claims 36, 40-43 link(s) inventions of Groups II-III and IV-V. The restriction requirement about the linked inventions is subject to the nonallowance of the linking claim(s), claims 36, 40-43. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions group I-IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups I to V are unrelated patentable distinct products. For example, the product of group I comprising diagnostic reagent in which the solid phage diagnostic reagent is sensitized with a recombinant antigen, whereas the groups II to V of products comprises a solid phage diagnostic reagent that is sensitized with carrier protein conjugated peptide antigen or carrier protein conjugated peptide antigens. They are not disclosed to be used together, and each of them has different patentable weight and requires different search. For example, the search for diagnostic agent with antigen peptide core, does not need to search NS4 or NS5 or vice versa.

4. Inventions group II-IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups II to V are unrelated patentable distinct products. For example, the product of group II comprising a solid phase diagnostic reagent that is sensitized with a carrier protein conjugated core peptide, whereas the groups III comprises a solid phage diagnostic reagent that is sensitized with carrier protein conjugated peptide antigen NS4, the group IV

comprises a solid phage diagnostic reagent that is sensitized with carrier protein conjugated peptide antigen NS5 and the product of group V comprises a solid phage diagnostic reagent that is sensitized with carrier protein conjugated peptide antigens of core, NS4 and NS5. They are all not disclosed to be used together and each of them has different patentable weight and requires different search. For example, the search for diagnostic agent with antigen peptide core does not need to search NS4 or NS5 or vice versa.

5. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group IV, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
03/19/2005